

### REMARKS

Claims 1-10 and 24-49 remain in this application. Claim 1 has been amended. Claims 11-23 have been canceled herein, without prejudice, as directed to non-elected species of the invention. Claims 24-49 have been added. Applicants submit that no new matter has been added with the foregoing amendments to the claims.

At the outset, Applicants thank the Examiner for granting a telephone interview on May 24, 2005. At the conclusion of the interview, the Examiner indicated that claims in substantially the same form as Claims 1, 24, and 37, provided above, would be allowable over the prior art of record.

Before addressing the merits of the grounds of rejection, Applicant provides the following brief description of the invention. The claimed invention generally relates to a respiratory device that provides improved sealing and gas delivery to a patient. Unlike the prior art respiratory devices, the claimed invention does not need to be sealed to the patient's face, and therefore avoids the problems of deficient sealing between the mask and the patient's face that result from wide variations in facial features among people and other factors, such as facial hair on the patient's face. In contrast to the prior art, the claimed invention does not have a bite block, which can cause jaw fatigue and stimulate gag reflexes. The claimed respiratory mask generally comprises an intraoral mouthpiece that is configured to fit between the patient's gums and lips, and a tubular extension that feeds into a central orifice defined by the mouthpiece.

The primary prior art reference cited by the Examiner in rejecting Claims 1-9 is Blachly (US 4,270,531). However, the structural features of the oropharyngeal airway-bite block assembly disclosed in Blachly make the disclosed assembly unsuitable as a respiratory mask. The oropharyngeal airway-bite block assembly in Blachly comprises a bite block (12) and an oropharyngeal airway tube (10). The design of the Blachly assembly is such that the patient must bite down on and maintain a sealing pressure on the bite block (12) in order to form an effective seal between the assembly and the

patient's mouth. The Blachly assembly cannot be used on an unconscious patient because the patient will not be able to maintain pressure on the bite block (12) to form a seal that prevents the leakage of gases to be delivered to the patient through the tube (10). Thus, the disclosed assembly is inoperable when the patient is unconscious.

Also, the airway tube (10) of the Blachly assembly extends over the patient's tongue and into the throat region. Column 3, lines 52-56; column 4, lines 40-41. Because the tube (10) extends into the patient's throat region, introduction of the tube (10) into the patient's mouth will stimulate gag reflexes in the patient. Therefore, the disclosed assembly is inoperable when the patient is conscious since it is not possible to introduce the assembly into the patient's mouth without gagging the patient. In a clinical setting, where the patient's life can depend on how quickly the clinician delivers gases (e.g., oxygen, air, etc.) to the patient, it is critical for the clinician to expeditiously introduce the respiratory mask to the patient and form an effective seal. The Blachly assembly is not suitable for ventilating a conscious person when time is of the essence, because the assembly will gag the patient, which can compound an already difficult situation, such as where a patient is uncooperative or experiencing a seizure. In short, the Blachly assembly is inoperable when the patient is unconscious because the patient cannot provide the requisite sealing pressure to the bite block (12), and is also inoperable when the patient is conscious because the airway tube (10) will gag the patient.

The Examiner rejected Claims 1, 3, 7, and 9 under 35 U.S.C. § 102(b) as being anticipated by Blachly. These rejections are respectfully traversed.

With respect to Claim 1, the Examiner asserts that Blachly discloses an oropharyngeal airway and bite block assembly that comprises a substantially oval and bowed sheet of material (12) that comprises an orifice (40), and a tubular extension (20) that feeds into the central orifice (40). However, a closer examination of Blachly reveals fundamental differences between the disclosed oropharyngeal airway-bite block assembly in Blachly and the respiratory mask recited in Claim 1. The oropharyngeal

airway tube (10) in Blachly comprises both the anterior portion (20) and a posterior portion (16) that extends over the patient's tongue and into the upper throat region which, as explained above, makes it likely that the tube (10) will stimulate gag reflexes in the patient. In contrast, Claim 1 recites a respiratory mask wherein "the proximal end of the tubular extension terminat[es] substantially coextensive with the inner surface of the sheet of material," which makes it possible to introduce and use the claimed respiratory mask inside the patient's mouth without stimulating gag reflexes.

Claims 3, 7, and 9, which depend from Claim 1, are patentable for the reasons stated above with respect to Claim 1, and because of the additional limitations set forth therein. Accordingly, Applicants request that the rejection of Claims 1, 3, 7, and 9 be withdrawn.

The Examiner rejected Claims 2 and 5 under 35 U.S.C. § 103(a) as being unpatentable over Blachly in view of Fitton (US 6,536,424). In order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations. M.P.E.P. § 2143 (Sept. 2004). As explained above, Blachly fails to teach or suggest a respiratory mask wherein "the proximal end of the tubular extension terminat[es] substantially coextensive with the inner surface of the sheet of material." Fitton does not disclose any feature that makes up for this deficiency of Blachly.

The Examiner rejected Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Blachly in view of Northway-Meyer (US 4,848,331). However, there is nothing in Northway-Meyer that makes up for the failure of Blachly to teach or suggest a tubular extension that terminates substantially coextensive with the inner surface.

The Examiner rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Blachly in view of Kulick (US Pub. No. 2002/0139375). However, there is nothing in Kulick that makes up for the failure of Blachly to teach or suggest a tubular extension that terminates substantially coextensive with the inner surface.

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable

over Blachly in view of Alfery (US 6,196,224). The Examiner asserts that it would have been obvious to modify Blachly's invention to provide an airway with at least one row of notches towards the distal end of the airway, in view of the fenestrations (390) in Alfery. The Examiner appears to equate the fenestrations (390) in Alfery to the row of notches, recited in Claim 8. As explained in the Specifications of the present application (page 16, lines 6-8), the notches allow the intraoral oropharyngeal airway to flex and follow the shape of the ventilated person's mouth as the airway is inserted. In contrast, the fenestrations (390) in Alfery are not designed to make the oral airway (300) flexible; rather, the fenestrations (390) are formed through the walls of the oral airway (300) to provide ventilation and "allow the passage of air through the nasal passages of the patient into the oral airway." Column 6, lines 48-49. Moreover, the curvature of the oral airway (100) in the absence of any fenestrations (390), as shown in Figures 4A and 4B, suggest that the fenestrations (390) in Figures 6A and 6B are not included to make the airway (300) follow the shape of the person's mouth and throat. Furthermore, there is nothing in Alfery that makes up for the failure of Blachly to teach or suggest a tubular extension that terminates substantially coextensive with the inner surface. Accordingly, Applicants request that the rejections of Claims 2, 4-6, and 8 be withdrawn.

The Examiner withdrew Claim 10 from consideration on the grounds that Claim 10 is directed to a non-elected species of the invention. Claim 10 depends from generic Claim 1, which Applicants submit is in condition for allowance. Applicants submit that Claim 10 is patentable for the reasons stated above with respect to Claim 1, and because of the additional limitations set forth therein.

Claims 24-49 have been added to the present application. Applicants submit that Claims 24-49 do not introduce new matter (see, e.g., Figures 2 and 3 as originally filed). Similar to Claim 1, Claim 24 recites a respiratory mask wherein "the proximal end of the tubular extension terminat[es] substantially coextensive with the inner surface of the mouthpiece." Because the prior art of record does not disclose such a feature, Applicants submit that Claim 24, as well as Claims 25-36 which depend from Claim 24,


are allowable. With respect to Claim 37, the prior art of record does not disclose a respiratory mask wherein the first and second lateral portions of the mouthpiece provide lateral flexibility and "facilitat[e] introduction and removal of the mouthpiece from the patient's mouth," as recited in Claim 37. As such, Applicants submit that Claim 37, as well as Claims 38-39 which depend from Claim 37, are allowable.

In view of the foregoing, the Applicants respectfully submit that Claims 1-10 and 24-49 are in condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested, and a timely Notice of Allowability is solicited. To the extent it would be helpful to placing this application in condition for allowance, the Applicants encourage the Examiner to contact the undersigned counsel and conduct a telephonic interview.

To the extent necessary, Applicants petition the Commissioner for a one-month extension of time, extending to June 24, 2005, the period for response to the Office Action dated February 24, 2005. Our check in the amount of \$135.00 is enclosed for the one-month extension of time (\$65.00) pursuant to 37 CFR §1.17(a)(1) and for the later presentation of three total claims in excess of twenty (\$75.00), pursuant to 37 C.F.R. § 1.16(c). In addition, the Commissioner is authorized to charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0639.

Respectfully submitted,

Date: June 1, 2005

  
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